



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,276	01/02/2004	Sebastiano Scarampi	033292-004	7478
21839	7590	03/26/2010		
BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404				EXAMINER
				GHALI, ISIS A D
ART UNIT		PAPER NUMBER		
1611				
NOTIFICATION DATE		DELIVERY MODE		
03/26/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com
offserv@bipc.com

Office Action Summary	Application No. 10/751,276	Applicant(s) SCARAMPI ET AL.
	Examiner Isis A. Ghali	Art Unit 1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 01 December 2009.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,37-41 and 44 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,37-41 and 44 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/96/08)
Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____

5) Notice of Informal Patent Application

6) Other: _____

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 12/01/2009.

Claims 1, 37-43 previously presented. Claims 42-43 are currently canceled and claim 44 is currently added.

Claims 1, 37-41 and 44 are pending and included in the prosecution.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 44 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Newly added claim 44 recites "the composition is effective achieving 17.66 $\mu\text{g}/\text{cm}^2/\text{hr}$ skin penetration of the caffeine or 0.1862 $\mu\text{g}/\text{cm}^2/\text{hr}$ skin penetration of the hydrocortisone". This is new matter. The claimed flux rates are only shown with Oil-A as presented by the tables in pages 37 and 38 and such flux rates were not shown as the superior flux rate as other oils showed higher flux rate, such as Oils-B, Oil-C, Oils-X, Oils-Y and Oils-Q. Further, the study was done on flow-through diffusion cell, and not skin as instantly claimed. In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "major proportion" in claim 1 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicant disclosed range of Gilsonite oil in the composition of at least 0.1%, and preferably between 0.1-80%, and more preferably between 2 and 50%. In view of

the disclosed range, and in absence of definition for the term "major proportion", any range within the disclosed range is considered "major proportion".

Regarding claim 44, the expression "at least about" renders the claim indefinite because it includes two contradicting terms that render the claim subject for more than one interpretation. The term "at least" does not permit values below 50%, while the term "about" permits values below 50%.

Response to Arguments

5. Applicant's arguments filed 12/01/2009 have been fully considered but they are not persuasive. Applicants argue that the phrase "the major proportion ingredient" appears in ¶ [0017] of the published version of the application. That paragraph discloses compositions for topical and transdermal administration comprising a bioactive agent and Gilsonite oil in various weight percents, along with, preferably, a pharmaceutically acceptable carrier. The adjective "major" commonly means "greater in number, quantity or extent."

In response to this argument, it is argued that the term "major proportion ingredient" is relative term. Nothing of record defines the term in terms of specific percentage or any other value. The claim does not recite the amount of other ingredients in order to predict the amount of Gilsonite oil. The claims' language does not exclude other ingredients in order to assume that the Gilsonite oil is present in major proportion of the composition. Applicants failed to define the expression "major proportion". Specification defined the amount of Gilsonite oil can be as low as 0.01%.

Even if the definition of the term "major" given its customary meaning known in the art, the claim does not define "major proportion" relative to what ingredient. In view of the term "about" the amount taught by the reference reads on the claimed amounts.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 41, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orlowski (CA 2,001,688) in view of Friedman et al. (US 7,074,392).

Currently amended claim 1 recites a composition for topical or transdermal administration consisting essentially of: (i) nicotine, caffeine or hydrocortisone; and (ii) Gilsonite oil, and wherein Gilsonite oil is the major proportion ingredient. Since claims are read in light of the specification, and since applicants disclosed at least 0.1% of Gilsonite oil in the composition, then the term "major proportion" will read on any range more than 0.1%. Claim 41 recites a composition for topical or transdermal administration consisting of: (i) nicotine, caffeine or hydrocortisone; and (ii) Gilsonite oil.

Orlowski teaches topical composition for treating human nails comprising 6.25% Gilsonite, mineral oil carrier that reads on excipients and enhancers, preservative, and 3% of soybeans that reads on the bioactive agent and enhancers (page 3, 1st paragraph; page 5, 3rd full paragraph; page 6, 1st paragraph; page 8, 2nd and 4th paragraphs). Gilsonite oil is a component of the Gilsonite, and Orlowski teaches composition comprising Gilsonite and mineral oil carrier. Therefore, some of the Gilsonite, if not all, will inevitably dissolve in the mineral oil carrier present in the composition releasing Gilsonite oil. Gilsonite inevitably dissolves in hydrocarbon solvent (mineral oil) because compounds and their properties are inseparable. Therefore, the composition taught by the reference contains Gilsonite oil. Orlowski teaches the

composition further comprising antibacterial and antifungal agents (page 3; page 5, last paragraph; page 6, 3rd paragraph).

The expression "consisting essentially of" limits the scope of the claim to the specified ingredients, and those that do not materially affect the basic and novel characteristics of the composition. *In re Janakirama-Rao*, 317 F 2d 951, 137 USPQ 893 (CCPA 1963). When applicant contends that modifying components in the reference's composition are excluded by the recitation of "consisting essentially of", applicant has the burden of showing the basic and novel characteristics of the claimed composition, i.e. showing that the introduction of these components would materially change the characteristics of applicant's composition. *In re De Lajarte*, 337 F 2d 870, 143 USPQ 256 (CCPA 1964).

Although Orlowski suggested bioactive agents including antibacterial agent in the composition applied to the nails, however, does not explicitly teach hydrocortisone, nicotine, or caffeine as instantly claimed by claims 1 and 41.

Friedman teaches sustained release nail treating composition comprising antibacterial agents and antipsoriatic agent, with hydrocortisone is preferred antipsoriatic agent in an amount of 0.1-10% (abstract; col.3, lines 36-39; col.4, lines 46-50; col.14, lines 45-49). The composition is suitable to treat nail and surrounding tissues and it reduces the unwanted side effects caused by high concentration of the antimicrobial agents (col.3, lines 24-28).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical composition for treating human nails

comprising Gilsonite and antimicrobial agent as taught by Orlowski, and further add hydrocortisone to the antimicrobial agent or replace antimicrobial agent with hydrocortisone taught by Friedman according to the condition to be treated. One would have been motivated to do so because Friedman teaches that antimicrobial agents can be administered with hydrocortisone to the nails and further teaches that hydrocortisone is one of the preferred active agents to treat psoriasis of the nails and surrounding tissues and composition comprising hydrocortisone reduces the unwanted side effects caused by high concentration of the antimicrobial agents. One would reasonably expected formulating topical composition for treating human nails comprising Gilsonite and antimicrobial agent and/or hydrocortisone that successfully treats the nail and surrounding tissues without any unwanted side effects.

Regarding the flux rate of caffeine and hydrocortisone as claimed by claim 44, one having ordinary skill in the art would determine the flux rate of the active agent based on the disorder to be treated.

Response to Arguments

10. Applicant's arguments filed 12/01/2009 have been fully considered but they are not persuasive.

Applicants argue that that the references as applied fail to teach or suggest the claimed composition wherein Gilsonite oil is present in a greater weight percent than other ingredients.

In response to this argument, it is argued that the instant claim 39 recites amount of Gilsonite oil from about 2 to about 50%, and the instant specification discloses the compositions may comprise amount as low as about 0.01% Gilsonite oil. By Applicant's own admission on page 8 of the arguments filed 06/22/2009, "Gilsonite oil in the formulation of Orlowski would constitute about 0.3% of the formulation"; which would meet the limitation of "major proportion" as discussed supra. Note: claim 1 does not recite any amounts and claim 39 recites the term "about". The specification discloses broad range. In absence of the definition of the claimed expression "major proportion" and in light of the proportions and ranges disclosed by the specification and in view of the term "about" recited by claim 39, the amount taught by Orlowski reads on the claimed ranges.

Applicants argue that the transitional phrase "consisting essentially of" limits the claims to the specified ingredients and those that do not materially affect the basic and novel characteristics of the claimed invention. In this case, the basic and novel characteristics include ability of Gilsonite oil to enable the bioactive agent to penetrate the skin. The cited references fail to recognize the superior and unexpected property of Gilsonite oil to enable the penetration of skin, nor do they teach or suggest any composition having any significant amount of Gilsonite oil. Instead, Orlowski uses Gilsonite (not Gilsonite oil), as a sealant and notes that it is substantially waterproof. The amount of Gilsonite oil in the formulation of Orlowski would constitute only about 0.3% of the formulation. The record fails to support the contention that 0.3% of Gilsonite

oil would be sufficient to achieve the basic and novel characteristics of the claimed invention, nor does the rejection supply any reason for one of ordinary skill in the art to increase the amount of Gilsonite oil beyond that which might be found in the composition of Orlowski.

In response to this argument, applicants' attention is directed to the scope of the present claims that is drawn to composition, and all the elements of the composition are taught by the combined prior art. The intended use of individual ingredients does not impart patentability to the claims. Regarding the expression "consisting essentially of", it is argued that the expression "consisting essentially of" limits the scope of the claim to the specified ingredients, and those that do not materially affect the basic and novel characteristics of the composition. *In re Janakirama-Rao*, 317 F 2d 951, 137 USPQ 893 (CCPA 1963). When applicant contends that modifying components in the reference's composition are excluded by the recitation of "consisting essentially of", applicant has the burden of showing the basic and novel characteristics of the claimed composition, i.e. showing that the introduction of these components would materially change the characteristics of applicant's composition. *In re De Lajarte*, 337 F 2d 870, 143 USPQ 256 (CCPA 1964). For the purposes of searching for and applying prior art, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising" and is therefore, inclusive or open-ended and does not exclude additional, unrecited elements. See MPEP 2111.03. Further, it has been held that omission of an element and its function is obvious if the function of the element is not desired. *Ex parte Wu*, 10

USPQ 2031 (Bd. Pat. App. & Inter. 1989). See also *In re Larson*, 340 F.2d 965, 144

USPQ 347 (CCPA 1965); and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975).

In regard to the properties of Gilsonite oil as penetration enhancer, it is understood that such property is a property of the oil and is present even if not explicitly disclosed; furthermore the properties of the Gilsonite oil is not a limitation of the instant claim and therefore, the reference encompasses the instant claims. The discovery of a new action underlying a known process does not make it patentable. *MEHL/Biophile*, 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. Also, it is irrelevant that the prior art observers did not recognize the property or function of the disputed claim; if the prior art inherently possessed that characteristic, it anticipates. See *Verdeegal Brothers, Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628,633, 2 U.S.P.Q.2d 1051, 1054 (Fed. Cir. 1987).

It is further argued that by Applicant's own admission, Gilsonite is soluble in aliphatic, aromatic and chlorinated hydrocarbon solvents. CA '688 discloses Gilsonite in mineral oil carrier. By the broadest reasonable interpretation, the Gilsonite in the presence of a hydrocarbon solvent (mineral oil) would inevitably lead to some if not all of the Gilsonite solubilizing into mineral oil to form Gilsonite oil. Further, Gilsonite oil is a component of Gilsonite, therefore when Gilsonite is dissolve in the hydrocarbon solvent, the Gilsonite oil will be present. With regard to the amount of Gilsonite oil, one having ordinary skill in the art would have been able to determine such amount according to the intended use. In any event the reference disclosed 6.25% Gilsonite. The amount of Gilsonite in the composition can be adjusted by person of ordinary skill in the art according to the drug used, specific intended use and site of application.

In addition, regarding applicant's arguments of unexpected superior results in the instant specification, it is the examiner's position that the data in the specification regarding increased flux rate of drugs are not unexpected results and therefore can not rebut *prima facie* obviousness. The examiner directs applicant's attention to MPEP 716.02 (a). "A greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness of the claims at issue." *In re Corkhill*, 711 F.2d 1496, 266 USPQ 1006 (Fed.Cir. 1985). *In Corkhill*, the claimed combination showed an additive result when a diminished result would have been expected. Furthermore, the MPEP states, "Expected beneficial results are evidence of obviousness of a claimed invention, just as unexpected results are evidence of unobviousness thereof." *In re Gershon*, 372 F.2d 535, 538, 152 USPQ 602, 604 (CCPA 1967). Further, it is argued that the

objective evidence of nonobviousness must be commensurate in scope with claims that evidence is offered to support. See in Greenfield and DuPont 197 USPQ 227 (CCPA 1978); In re Boesch and Slaney 205 USPQ 215 (CCPA 1980); and In re Tiffin and Erdman 170 USPQ 88 (CCP 1971). In instant case, the examples show variation and inconsistency in the flux rate with Oils 1, A, B, C, X, Y and Q. Where a valid case of *prima facie* obviousness has been established, the burden is shifted to applicant to demonstrate that a claimed functional property is applicable to the claim in its broad scope: *In re Greenfield*, 197 USPQ 227, 229 (CCPA 1978). (Holding that despite the fact that the rejection was one of obviousness and not anticipation, the burden was nevertheless on applicant to provide factual verification of the alleged functional property). Thus, even assuming *arguendo* that applicant has shown that a specific combination of components might exhibit unexpected property, this has not been shown for the broad genus of all ranges of combination currently claimed.

Applicants argue that the references as applied fail to teach or suggest the claimed composition, "consisting of (i) nicotine, caffeine or hydrocortisone; and (ii) Gilsonite oil" as claimed by claim 41. The transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim. MPEP 2111.03. The rejection of claim 41 fails to provide any rationale as to why one of ordinary skill in the art would arrive at the claimed composition.

In response to this argument, it is argued that the expression "consisting of, Orlowski teaches composition consisting of Gilsonite oil, soybean oil, mineral oil and

cresylic acid. Soybean oil, mineral oil and cresylic acid all read on carrier for the composition. It has been held that omission of an element and its function is obvious if the function of the element is not desired. *Ex parte Wu*, 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989). See also *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965); and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975).

11. Claims 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orlowski (CA 2,001,688) in view of Friedman (US 7,074,392) and further in view of Forrest (US Patent No. 1,573,765, current USPTO form 892).

The combined teaching of Orlowski and Friedman are previously discussed as set forth in this office action.

Orlowski however does not specifically teach the viscosity and the specific gravity of Gilsonite oil as instantly claimed by claims 37 and 42. Orlowski does not specifically teach the amount of the oil in the composition. However, one having ordinary skill in the art would have been able to determine the viscosity and specific gravity of oil used in the topical composition as well as the amount of oil according to its specific intended use, drug used and site of application.

Orlowski further differs from the instant claims insofar as it does not disclose the specific fraction of Gilsonite as claimed.

Forrest teaches Gilsonite can be made the basis for the production of a great variety of commercially useful products (col.3, lines 21-23), wherein the specific properties are so diverse that they can generally be utilized to the best advantage when

the different products of Gilsonite are separated from one another by fractionation (col.4, lines 75-78 and 95) and purification (col.11, line 19). Forrest discloses the said properties include use as an emulsifying agent (col.12, line 113-114). Forrest teaches Gilsonite oil fractions with specific gravities of 0.870 (col.12, line 94), 0.927 and 0.933 (col.13, lines 21-26). Forrest teaches viscosities within the claimed range in the chart at (col.14, lines 75-85).

Purer forms of known products may be patentable, but the mere purity of a product, by itself, does not render the product unobvious. See MPEP 2144.01, VII. Therefore, it would have been obvious to have used the purer form of the Gilsonite in the aqueous emulsion composition of Orlowski motivated by the desire to use a product that has advantageous properties, i.e. emulsifying properties, when the product is purified as disclosed by Forrest.

In regards to the specific fraction of Gilsonite oil, Forrest teaches the fraction of Gilsonite oil having a viscosity of about 5 to about 1,000 cps at 25°C, and specific gravity of about 0.8 to 0.95. Therefore, the composition of Orlowski in view of Forrest meets the limitations claimed by claims 37-40, 42-43. Motivation to select Gilsonite oil having specific properties will logically flow from the cosmetic art based on the intended use of Gilsonite oil and composition incorporating it.

Response to Arguments

12. Applicant's arguments filed 12/01/02009 have been fully considered but they are not persuasive.

Applicants argue that the record fails to establish any need for an emulsifier in the compositions of Orlowski or Friedman, nor any other reason why one of ordinary skill in the art would combine the references in the manner suggested by the rejection. Applicants argue that the obviousness rejection of these claims fails to meet the legally-required standard. Although the Examiner did not expressly identify a specific rationale for the rejection, it appears to be the rationale of "simple substitution of one known element for another to obtain predictable results." MPEP 2143.B. Furthermore, there is no factual support for one of ordinary skill in the art could have substituted the Gilsonite oil of Forrest for the solid mineral Gilsonite of Orlowski, and would have predicted success in doing so.

In response to these arguments, it is argued that Orlowski teaches soybean oil which is an emulsifier that can be replaced by Gilsonite oil. It is *prima facie* obvious to substitute one functional equivalent for another functionally equivalent emulsifier. In KSR, the Supreme Court particularly emphasized "the need for caution in granting a patent based on the combination of elements found in the prior art," USPQ2d at 1395, and discussed circumstances in which a patent might be determined to be obvious. "*In United States v. Adams,...* [t]he Court recognized that **when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.**" USPQ2d at 1395.

Court further stated that:

"When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. USPQ2d at 1396."

"When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. USPQ2d at 1396."

Orlowski teaches composition for nail treatment comprising Gilsonite as a whole and mineral oils that inevitably solubilize Gilsonite liberating its oils. Forrest teaches Gilsonite can be made the basis for the production of a great variety of commercially useful products, wherein the specific properties are so diverse that they can generally be utilized to the best advantage when the different products of Gilsonite are separated from one another by fractionation and purification. Forrest teaches the said properties include use as an emulsifying agent. Therefore other uses of fractioning products are suggested, and one having ordinary skill in the art would realize its suitability in use in

topical composition in view of the teaching of Orlowski. Forrest teaches Gilsonite oil fractions with specific gravities of 0.870 and 0.933. Forrest teaches viscosities within the claimed range in the chart at col.14, lines 75-85. Purer forms of known products may be patentable, but the mere purity of a product, by itself, does not render the product unobvious. See MPEP 2144.01, VII. Therefore, it would have been obvious to have used the purer form of the Gilsonite in the aqueous emulsion composition of Orlowski motivated by the desire to use a product that has advantageous properties, i.e. emulsifying properties, when the product is purified as disclosed by Forrest.

In regards to the specific fraction of Gilsonite oil, Forrest teaches the fraction of Gilsonite oil having a viscosity of about 5 to about 1,000 cps at 25°C, and specific gravity of about 0.8 to 0.95. Therefore, the composition of Orlowski in view of Forrest meets the limitations claimed by claims 19-23, 25-26. Motivation to select Gilsonite oil having specific properties will logically flow from the cosmetic art based on the intended use of Gilsonite oil and composition incorporating it.

Regarding function of Gilsonite oil as penetration enhancer, it is argued that discovery of a new action underlying a known process does not make it patentable. Also, it is irrelevant that the prior art observers did not recognize the property or function of the disputed claim; if the prior art possessed that characteristic, it makes it obvious. Oils are known to use in the art to enhance delivery of actives through the skin, see US 5,460,821 by Masiz.

Further, in response to applicant's argument that "the record fails to establish why one of ordinary skill in the art would combine the references in the manner

suggested by the rejection", it is argued that the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

The present invention as a whole is taught by the combined teachings of references, and it would have been *prima facie* obvious in the meaning of USC 103 (a).

Applicants argue that as already well-established in this case, raw Gilsonite and Gilsonite oil have distinct chemical compositions with substantially distinct properties. Declaration of Gary David Fisher, filed August 27, 2008, ¶ 4. The rejections fails to supply adequate reasoning as to why one of ordinary skill in the art would select Gilsonite oil as a component of the claimed compositions for topical or transdermal administration.

In response to this argument, it is argued that applicants admit that Gilsonite is soluble in aliphatic, aromatic and chlorinated hydrocarbon solvents. Orlowski discloses Gilsonite in mineral oil carrier. By the broadest reasonable interpretation, the Gilsonite in the presence of a hydrocarbon solvent (mineral oil) would inevitably lead to some if not all of the Gilsonite solubilizing into mineral oil to form Gilsonite oil. Further, Gilsonite oil is a component of Gilsonite, therefore when Gilsonite is dissolve in the hydrocarbon solvent, the Gilsonite oil will be present.

In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in

the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

IG